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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,896 | 11/21/2003 | John N. Nuss | PP-01677.006 | 1440 |

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| EXAMINER |
|-------------------------------|
| BALASUBRAMANIAN, VENKATARAMAN |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1624 | |

| MAIL DATE | DELIVERY MODE |
|------------|---------------|
| 10/19/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,896

Applicant(s)

NUSS ET AL.

Examiner

/Venkataraman
Balasubramanian/

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27,31,32,37-43 and 45-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-27,31,32,37-43,45 and 46 is/are allowed.
- 6) ☒ Claim(s) 47-53 is/are rejected.
- 7) ☒ Claim(s) 54-58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, which included cancellation of claim 44, addition of new claims 47-58 and amendment to claims 1-10, 12, 16, 19-22, 25, 32 and 46, filed on 7/18/2007 has been entered.

Claims 1-27, 31, 32, 37-43 and 45-58 are now pending.

In view of applicants' response, the 112 second paragraph rejection and all prior art rejections made in the previous office action have been either obviated due amendment to claims or rendered moot due to cancellation of rejected claim.

The following new rejections are applied to the newly added claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Narr et al., DE 2341925.

Narr et al., teaches several 2,4,5,6-tetrasubstituted pyrimidine compounds useful as antithrombotics, which include compounds, composition and method of use embraced in the instant claims. See formula I. Note with the given definition of various R₁, R₂, R₄ and R₃ groups, the compounds taught by Narr et al., are also generically embraced in the instant claims. See entire document for details of the invention.

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Especially see page 83, example 135, page 89, example 157 and page 90, example 159 for some examples of compounds made. See also page 89, example 156.

Claims 47-49 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Falco et al., British Journal of Pharmacology and Chemotherapy, 6, 185-200, 1951. CA 46: 27482, 1952. CAPLUS Abstract provided.

See the compound shown in the CAPLUS Abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narr et al., DE 2341925.

Teachings of Narr et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Narr et al., teaches several 2,4,5,6-tetrasubstituted pyrimidine compounds useful as antithrombotics, which include compounds, composition and method of use embraced in the instant claims. See formula I. Note with the given definition of various R_1 , R_2 , R_4 and R_3 groups, the compounds taught by Narr et al., are also generically embraced in the instant claims. See entire document for details of the invention. Especially see page 83, example 135, page 89, example 157 and page 90, example 159 for some examples of compounds made. See also page 89, example 156.

Narr et al. differs from the instant claims in exemplifying only few pyrimidine compounds bearing instant Y-X, W, R_1 and R_2 choices.

However, Narr et al. teaches equivalency of those compounds (examples 1-225) taught in pages 10-111 with those generically recited in pages 1-3 for formula I.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Narr et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Allowable Subject Matter

Claims 54-58 are objected to as being dependent upon a rejected base claim, but would be allowable, barring finding of any prior art in a subsequent search, if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-27, 31, 32, 37-43, 45 and 46, barring finding of any prior art in a subsequent search, would be allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from

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8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

10/15/2007